

LABORATORY AND PATHOLOGY SERVICES

ELIGIBLE PROVIDERS

In order to receive payment, all eligible servicing and billing provider's National Provider Identifiers (NPI) must be enrolled with South Dakota Medicaid. Servicing providers acting as a locum tenen provider must enroll in South Dakota Medicaid and be listed on the claim form. Please refer to the [provider enrollment chart](#) for additional details on enrollment eligibility and supporting documentation requirement.

South Dakota Medicaid has a streamlined enrollment process for ordering, referring, and attending physicians that may require no action on the part of the provider as submission of claims constitutes agreement to the South Dakota Medicaid Provider Agreement.

Laboratories must have a current CLIA certificate.

ELIGIBLE RECIPIENTS

Providers are responsible for checking a recipient's Medicaid ID card and verifying eligibility before providing services. Eligibility can be verified using South Dakota Medicaid's [online portal](#).

The following recipients are eligible for medically necessary services covered in accordance with the limitation described in this chapter:

Coverage Type	Coverage Limitations
Medicaid/CHIP Full Coverage	Medically necessary services covered in accordance with the limitations described in this chapter.
Medicaid – Pregnancy Related Postpartum Care Only (47)	Coverage restricted to family planning and postpartum care only.
Qualified Medicare Beneficiary – Coverage Limited (73)	Coverage restricted to co-payments and deductibles on Medicare A and B covered services.
Medicaid – Pregnancy Related Coverage Only (77)	Coverage restricted to pregnancy related services only including medical issues that can harm the life of the mother or baby.
Unborn Children Prenatal Care Program (79)	Coverage restricted to pregnancy related services only including medical issues that can harm the life of the mother or baby.
Medicaid Renal Coverage up to \$5,000 (80)	Coverage restricted to outpatient dialysis, home dialysis, including supplies, equipment, and special water softeners, hospitalization related to renal failure, prescription drugs necessary for

dialysis or transplants not covered by other sources and non-emergency medical travel reimbursement to renal failure related appointments.

Refer to the [Recipient Eligibility](#) manual for additional information regarding eligibility including information regarding limited coverage aid categories.

COVERED SERVICES AND LIMITS

General Coverage Principles

Providers should refer to the [General Coverage Principles](#) manual for basic coverage requirements all services must meet. These coverage requirements include:

- The provider must be properly enrolled;
- Services must be medically necessary;
- The recipient must be eligible; and
- If applicable, the service must be prior authorized.

The manual also includes non-discrimination requirements providers must abide by.

Laboratory Services Coverage

South Dakota Medicaid covers medically necessary laboratory tests for diagnostic and treatment purposes. Services must:

- Be ordered and provided under the direction of a recipient's treating physician or other licensed practitioner who gives a consultation or treats a specific medical problem within his or her scope of practice as defined by state law;
- The service must yield results that are used by the treating physician or other licensed practitioner in the screening, diagnosis, or management of a recipient's specific medical problem; and
- Be allowed under the laboratory's CLIA certification if the service is classified under the CLIA program.

Some laboratory services require a prior authorization. Refer to the [Prior Authorization](#) manual for additional information.

Certain procedures are a combination of a physician or other licensed practitioner professional component and a technical component.

Professional Components

The professional component includes: examination of patient when indicated, performance or supervision of the procedure, interpretation and written report of the examination. Professional components should be reported by appending modifier 26 to the usual procedure code number.

Drug Screening

South Dakota Medicaid covers most drug testing that are medically necessary. Providers must document medical necessity in the recipient's medical record and include it in the plan of care. Documentation should specify how the test results will be used to guide decision making.

Drug or drug classes for which screening is performed, should be based on those likely to be present based on the recipient's medical history or current clinical presentation. A physician or other licensed practitioner must order the drug analysis. Standing orders or orders to "conduct additional testing as needed" are not sufficiently detailed to demonstrate medical necessity.

Genetic Testing

Diagnostic genetic testing must meet the following criteria:

- The recipient displays clinical features of a suspected genetic condition; or
- The genetic condition must be associated with a significant medical condition; and
- The results of the genetic testing must result in an evidence-based change in the active treatment plan.

Tests for conditions that are treated symptomatically are not appropriate because the treatment would not change.

Genetic Tests Exempt from Prior Authorization

The following genetic tests do not require prior authorization:

Genetic Testing Exempt from Prior Authorization as of October 2019	
CPT Code	Description
81170	ABL1 gene
81206	BCR/ABL1 gene major breakpoint
81207	BCR/ABL1 gene minor breakpoint
81208	BCR/ABL1 gene other breakpoint
81218	CEBPA gene full sequence
81219	CALR gene common variants
81235	EGFR gene common variants
81242	FANCC gene
81243	FMR1 gene detection
81245	FLT3 gene
81246	FLT3 gene analysis
81250	G6PC gene
81255	HEXA gene

81256	HFE gene
81261	IGH@ gene rearrange amplified methodology
81262	IGH@ gene rearrange direct probe
81263	IGH@ variable regional mutation
81264	IGK@ rearrangement clonal population(s)
81265	STR markers specimen analysis
81266	STR markers specimen analysis additional
81267	Chimerism analysis no cell selection
81268	Chimerism analysis w/cell selection
81270	JAK2 gene
81287	MGMT gene methylation analysis
81310	NPM1 gene
81315	PML/RARalpha common breakpoints
81316	PML/RARalpha single breakpoint
81340	TRB@ gene rearrangement amplification
81341	TRB@ gene rearrangement direct probe
81342	TRG@ gene rearrangement analysis
81506	Endocrinology assay seven analytes
81507	Fetal aneuploidy trisomy risk
81508	Fetal congenital abnormalities two proteins
81509	Fetal congenital abnormalities three proteins
81510	Fetal congenital abnormalities three analytes
81511	Fetal congenital abnormalities four analytes
81595	Cardiology mRNA

Genetic Testing Prior Authorization

Most genetic testing requires a prior authorization. To obtain authorization, the provider must complete the applicable genetic testing prior authorization form available on the department's [website](#). The department will determine whether the test meets the prior authorization criteria. South Dakota Medicaid's genetic testing criteria are available in the [Prior Authorization Manual](#).

aCGH Criteria

aCGH testing is covered with a prior authorization when the criteria below has been met in addition to the general genetic testing criteria. All of the following conditions must be met:

- Any indicated biochemical tests for metabolic disease have been performed, and results are nondiagnostic.
- FMR1 gene analysis for (for Fragile X), when clinically indicated, is negative.
- In addition to a diagnosis of nonsyndromic Developmental Disability, Intellectual Disability, or Autism Spectrum Disorder, the child has one or more of the following:
 - Two or more major malformations.
 - A single major malformation or multiple minor malformations in an infant or child who is also small-for-dates.
 - A single major malformation and multiple minor malformations.
- The results for genetic testing have the potential to impact clinical management of the patient through an evidence based change to the treatment plan.

BRCA Criteria

BRCA genetic mutation testing will be covered with a prior authorization for breast/ovarian cancer in women and breast cancer in men will be approved in cases where the results will impact the care of the patient. Criteria in (1) or (2) must be met:

- Patient is identified as high-risk for BRCA mutation and is age 19 or older. High-risk includes the following factors:
 - Women of Ashkenazi Jewish descent (or other ethnicity/population for which founder mutations in the BRCA gene have been identified) with any first degree relative or two second relatives on the same side of the family with breast or ovarian cancer. (Diagnosis codes: Z803 or Z8041)
 - Women of other ethnicities who have one or more of the following factors:
 - First or second degree relative with breast cancer (Diagnosis Z803) and at least one of the following:
 - i. diagnosed at age 45 or younger
 - ii. diagnosed at age 50 or younger and limited or unknown family history or with one additional first or second degree relative diagnosed with breast cancer at any age
 - iii. diagnosed at age 60 or younger with triple-negative breast cancer
 - First or second degree relative with 2 breast primaries (Diagnosis Z803) and the first primary diagnosed at age 50 or younger
 - First or second degree relative with breast cancer (Diagnosis Z803) diagnosed at any age and 1 or more of the following:
 - i. One additional first or second degree relative with breast cancer diagnosed at age 50 years or younger
 - ii. Two or more first or second degree relatives on the same side of the family with epithelial ovarian cancer
 - iii. Three or more first or second degree relatives on the same side of the family with breast cancer diagnosed at any age
 - iv. First or second degree relative with both breast and epithelial ovarian cancer

- Patient has a personal history of breast cancer: (Diagnosis Z853)
 - diagnosed before age 60 and triple-negative
 - diagnosed before age 45
 - diagnosed at any age with a first or second degree relative with breast Cancer diagnosed before age 50
 - first or second degree relative on the same side of the family with ovarian cancer

Factor V Criteria

Factor V Leiden testing (CPT 81241) is covered without prior authorization. For pregnant women, the testing will be covered for a primigravida who also has a first degree relative with a history of thromboembolism and a positive Factor V Leiden test, or if she has had a previous thromboembolism and no previous Factor V Leiden testing. For all other non-pregnant recipients, the testing will be covered if the recipient meets one of the following criteria:

- Age less than 50 with any venous thrombosis; or
- Myocardial infarction in female smokers under age of 50; or
- Recurrent venous thrombosis; or
- Relatives of individuals with venous thrombosis under age of 50; or
- Venous thrombosis and a strong family history of thrombotic disease; or
- Venous thrombosis in women taking oral contraceptives; or
- Venous thrombosis in unusual sites (such as hepatic, mesenteric, and cerebral veins).

Fragile X Criteria

Fragile X detection (CPT 81243) is covered without prior authorization when the recipient meets the following criteria:

- The individual is age 0 to 20; and
- The results of the test will affect the individual's plan of care; and
- The individual has an intellectual disability, developmental delay, or autism spectrum disorders.

Fragile X gene characterization (CPT 81244) requires prior authorization.

Cologuard

Cologuard is a covered service once every three years when the eligible recipient has met the following criteria:

- Age 50 to 85 years,
- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and
- At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or an adenomatous polyp, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

Pharmacies

Pharmacies may provide and bill for a strep test, CPT 87880, or a flu test, CPT 87804, if the test is

authorized under a collaborative agreement with a physician. The physician must be an enrolled South Dakota Medicaid provider. The test must be billed on a CMS 1500 claim form. The pharmacy must obtain a referral from the recipients' Primary Care Provider or Health Home, if the recipient is part of one of those programs. A physician's order/referral must be included on the claim form. Pharmacies must submit strep tests and flu test with the QW modifier.

Indian Health Services (IHS) and Tribal 638 Facilities

IHS and tribal 638 facilities should refer to the [Indian Health Services and Tribal 638 Facilities](#) manual for additional information regarding coverage, reimbursement, and claim instructions.

FQHC and RHCs

FQHCs and RHCs should refer to the [FQHC and RHC Services](#) manual for additional information regarding coverage, reimbursement, and claim instructions.

NON-COVERED SERVICES

General Non-Covered Services

Providers should refer to [ARSD 67:16:01:08](#) or the [General Coverage Principles](#) manual for a general list of services that are not covered by South Dakota Medicaid.

Non-Covered Laboratory Services

Non-covered services include the following:

- Routine handling charges (99000-90001);
- Stat fees (S3600-S3601);
- Blood typing for paternity testing (CPT codes 86910 and 86911)
- Postmortem examination (CPT codes 88000-88005);
- Reproductive medicine procedures (CPT codes 89250-89398);
- G code drug screening tests (G0480-G0483 and G0659); and
- NOS drug screening tests (80375-80377).

Non-Covered Genetic Testing

South Dakota Medicaid does not cover Genetic testing services under the following circumstances:

- Testing for information for the recipient without impacting treatment.
- Tests performed for the medical management of other family members, including future family planning.
- History, physical examination, pedigree analysis, or completion of conventional diagnostic studies has given a definitive diagnosis.
- A genetic test was previously performed for the recipient to provide a conclusive diagnosis of the same genetic disorder.

DOCUMENTATION REQUIREMENTS

General Requirements

Providers must keep legible medical and financial records that fully justify and disclose the extent of services provided and billed to South Dakota Medicaid. These records must be retained for at least 6 years after the last date a claim was paid or denied. Please refer to the [Documentation and Record Keeping](#) manual for additional requirements.

REIMBURSEMENT AND BILLING

Timely Filing

South Dakota Medicaid must receive a provider's completed claim form within 6 months following the month the service was provided. Requests for reconsiderations will only be considered if they are received within the timely filing period or within 3 months of the date a claim was denied. The time limit may be waived or extended by South Dakota Medicaid in certain circumstances. Providers should refer to the [General Claim Guidance](#) manual for additional information.

Third-Party Liability

Medicaid recipients may have one or more additional source of coverage for health services. South Dakota Medicaid is generally the payer of last resort, meaning Medicaid only pays for a service if there are no other liable third-party payers. Providers must pursue the availability of third-party payment sources and should use the Medicare Crossover or Third-Party Liability billing instructions when applicable. Providers should refer to the [General Claim Guidance](#) manual for additional information.

Reimbursement

A claim must be submitted at the provider's usual and customary charge. Payment is limited to the lesser of the provider's usual and customary charge or the payment amount established on the department's fee schedule [website](#). As required by 1903(i)(7) of the Social Security Act and the South Dakota Medicaid State Plan the established fee for clinical diagnostic laboratory services is the Medicare established fee. Laboratory procedure not listed on the fee schedule are paid at 60 percent of the provider's usual and customary charge.

Midlevel Practitioners

Laboratory services provided by a physician assistant, nurse practitioner, or clinical nurse specialist are reimbursed at the same rate as a physician.

Outpatient Hospital Services

Except for Medicare outpatient prospective payment system (OPPS) hospitals, outpatient laboratory services are reimbursed according to the lesser of the provider's usual and customary charge or fee schedule methodology referenced above. OPPS are reimbursed according to this methodology if the services do not package. Costs for outpatient laboratory services incurred within three days immediately preceding an inpatient stay are included in the inpatient charges unless the outpatient laboratory service is not related to the inpatient stay. This provision applies only if the facilities providing the services are owned by the same entity.

Modifiers

If the procedure is a combination of a professional component and a technical component, the 26

modifier must be appended to the claim for the professional component and the TC modifier must be appended to the claim for the technical component. Procedure codes with Modifier 26 appended are reimbursed at the lesser of the provider's usual and customary charge or 30 percent of the established fee. Procedure codes with Modifier TC appended are reimbursed at the lesser of the provider's usual and customary charge or 30 percent of the established fee. If no fee is established, the claim is reimbursed 40 percent of the provider's usual and customary charge.

Claim Instructions

General Requirements

The laboratory that performed the test must submit the claim for the test. However, a laboratory participating in South Dakota Medicaid that did not perform the test may submit the claim for the test only when the participating lab cannot complete the test as ordered by the referring physician and the outside lab receiving the applicable test does not accept South Dakota Medicaid. The date of service is the date the specimen was drawn. Do not bill a date span for services defined as multiple treatments or units of service.

Multi-Channel Laboratory Tests

Do not separately report individual laboratory tests that are components of a multichannel test analysis (lab panel). For example, if you perform CPT codes 82330, 82374, 82435, 82565, 82947, 84132, 84295, and 84520 on the same date of service only report CPT code 80047 for the panel. Each test billed under the panel must be medically necessary. Tests that are not part of lab panel should be billed on a separate line of the claim form.

Modifiers

If applicable, the claim must identify the modifying circumstance of a service or procedure by appending modifier 26 or modifier TC to the procedure code.

Professional Services

Claims for professional services including inpatient and outpatient professional services must be submitted on a CMS 1500 claim form or via an 837P electronic transaction. Detailed claim form instructions are available on our [website](#).

Facility Services

Outpatient hospital services and inpatient hospital services must be billed on a UB-04 claim form or via an 837I electronic transaction. Detailed claim form instructions are available on our [website](#). For an inpatient laboratory test, the hospital must submit the claim for the test on the patient's inpatient hospital claim.

Unlisted CPT Codes

Unlisted or not otherwise classified codes may be reported on a claim if the service is not listed in the CPT codebook. Before considering using an unlisted or NOC, procedure code, you must determine if another more specific code could describe the procedure or service being performed or provided. The following unlisted codes pend for review by South Dakota Medicaid and the claim must be submitted with documentation to justify the use of the unlisted procedure code and to describe the procedure or service rendered:

- 84999 – Unlisted chemistry or toxicology procedure
- 87999 – Unlisted microbiology procedure
- 88299 - Unlisted cytogenetic study

If the documentation includes multiple tests, the provider must note which test is being claimed with the unlisted code.

The following unlisted codes must be prior authorized by South Dakota Medicaid prior to being provided:

- 81479 – Unlisted molecular pathology
- 81599 – Unlisted multianalyte assay procedure with algorithmic analysis

DEFINITIONS

1. "Other licensed practitioner," a physician assistant, nurse practitioner, clinical nurse specialist, nurse midwife, or nurse anesthetist who is licensed by the state to provide services and is performing within their scope of practice under the provisions of SDCL title 36;
2. "Prior authorization," written approval issuing authorization by the department to a provider before certain covered services may be provided;
3. "Usual, customary charge" or "usual and customary," the individual provider's normal charge to the general public for a specific service on the day the service was provided within the range of charges made by similar providers for such services and consistent with the prevailing market rates in the geographic area for comparable services;

REFERENCES

- [Administrative Rule of South Dakota \(ARSD\)](#)
- [South Dakota Medicaid State Plan](#)
- [Code of Federal Regulations](#)

QUICK ANSWERS

1. **If providing both the technical and professional components of a lab, is a modifier required?**

No, bill the applicable CPT code with no modifier.